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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/663,181	09/15/2003	Steven Z. Wu	50623.334	1431

7590 03/26/2007

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EXAMINER	
SHEIKH, HUMERA N	
ART UNIT	PAPER NUMBER
1615	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/26/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/663,181	WU ET AL.	
	Examiner	Art Unit	
	Humera N. Sheikh	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 December 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *25-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *25-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

Receipt of the Response to Non-Final Office Action and Applicant's Arguments/Remarks, all filed 12/21/06 is acknowledged.

The 35 U.S.C. 101 Statutory Double Patenting rejections of claims 25-33 over claims 25-33 of 10/293,175 has been hereby *withdrawn*, in view of the fact that the claims entered as a provisional amendment for 10/293,175 were entered in error and were a duplicate of claims 25-33 of application 10/663,181.

Claims 25-33 are pending in this action. Claims 1-24 have been cancelled. No claims have been amended. Claims 25-33 remain rejected.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 25-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yang *et al.* (WO 01/01890 A1).

The instant invention is drawn to a drug-loaded particle formulation method comprising: adding polymeric particles containing a therapeutic substance to a fluid form of an implantable medical device coating material; and solidifying the coating material to a film layer wherein the film layer includes the polymeric particles containing the therapeutic substance.

Yang *et al.* (WO '890) teach stents having polymeric coatings for controllably releasing an active agent, methods for coating a stent and methods for inhibiting restenosis (see Abstract and Claims). The stent has a stent body, a coating disposed over at least a portion of the body, and an active agent releasably dispersed in at least part of the portion of the coating. The coating can include a blend of first and second co-polymers (page 3, line 22 – pg. 4, line 6). The stent can be coated by spraying the stent with a solution or dispersion of polymer, active agent and solvent. The solvent can be evaporated, leaving a coating of polymer and active agent. The active agent can be dissolved and/or dispersed in the polymer. In some embodiments, the co-polymers can be extruded over the stent body (pg. 4, lines 12-16).

Yang *et al.* teach at page 7, lines 9-10, that a therapeutic agent can be incorporated into a polymer and applied to the stent as a polymeric surface treatment. Drugs and treatments utilize anti-thrombogenic agents, anti-angiogenesis agents, anti-proliferative agents, growth factors and radiochemicals. Specific examples of therapeutic agents are disclosed on page 7, lines 15-17. In a preferred embodiment, the active agent or therapeutic substance is a restenosis-inhibiting agent (pg. 9, lines 3-4). Processes for surface treatment are disclosed on page 7, lines 18-23. Suitable polymeric materials are disclosed at page 6, line 17 – pg. 7, line 4).

With regards to instant claim 30, which recites 'polymeric particles made by a water-in-oil emulsion method', it is the position of the Examiner that this limitation imparts a future-intended use limitation, which affords no patentable weight to the claims. The prior art teaches a similar method of coating stents, whereby the stent comprises first and second co-polymers,

active agent and solvent, wherein the solvent is evaporated, leaving a coating of polymer and active agent. This method clearly reads on the method claimed by Applicant(s).

With regards to instant claim 31, which recites 'polymeric particles having a hydrogel consistency', it is the position of the Examiner that this limitation is clearly met by the teachings of Yang *et al.* Yang *et al.* employs similar polymeric materials as utilized by Applicant, and thus the polymeric particles (of Yang *et al.*) would have similar characteristics and impart similar effects, as the polymeric materials of the instant invention, thus including a 'hydrogel consistency' as claimed herein. Applicants have not demonstrated any unusual or surprising results, which accrue from the instantly claimed components or limitations, since the prior art initially recognizes and teaches drug-particle formulation methods entailing similar method steps, used for the same field of endeavor and to treat the same problems as that desired by Applicant(s).

Thus, it is the position of the Examiner that given the explicit teachings of Yang *et al.*, the instant invention, when taken as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 25-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berg *et al.* (U.S. Pat. No. 5,464,650).

The instant invention is drawn to a drug-loaded particle formulation method comprising: adding polymeric particles containing a therapeutic substance to a fluid form of an implantable medical device coating material; and solidifying the coating material to a film layer wherein the film layer includes the polymeric particles containing the therapeutic substance.

Berg *et al.* ('650) teach a method for making an intravascular stent by applying to the body of a stent a solution, which includes a solvent, a polymer dissolved in the solvent and a therapeutic substance dispersed in the solvent and then evaporating the solvent. The inclusion of a polymer in intimate contact with a drug on the stent allows the drug to be retained on the stent during expansion of the stent and also controls the administration of the drug following implantation (see Abstract, Claims and column 2, lines 30-40). The method can be applied by immersing the stent into the solution or by spraying the solution onto the stent (col. 2, lines 40-44). Processes for preparing the coated stent are also disclosed on column 3, line 52 – col. 4, line 34, wherein it is taught that a solution, which includes a solvent, polymer dissolved in the solvent and a therapeutic substance dispersed in the solvent is first prepared. The solution is applied to the stent and the solvent is allowed to evaporate, thereby leaving on the stent surface a coating of the polymer and the therapeutic substance.

Suitable polymers are disclosed at column 4, line 35 – col. 5, line 7. Suitable therapeutic substances are disclosed at column 2, lines 55-62.

The intravascular stents of Berg *et al.* are directed towards reducing the incidence of restenosis (col. 1, lines 9-67).

With regards to instant claim 30, which recites 'polymeric particles made by a water-in-oil emulsion method', it is the position of the Examiner that this limitation imparts a future-intended use limitation, which affords no patentable weight to the claims. The prior art teaches a similar method of coating stents, whereby the stent solution includes a solvent, a polymer

dissolved in the solvent and a therapeutic substance dispersed in the solvent and then evaporating the solvent. This method clearly reads on the method claimed by Applicant(s).

With regards to instant claim 31, which recites 'polymeric particles having a hydrogel consistency', it is the position of the Examiner that this limitation is met by the teachings of Berg *et al.* Berg *et al.* employs similar polymeric materials as utilized by Applicant, and thus the polymeric particles (of Berg *et al.*) would have similar characteristics and impart similar effects, as the polymeric materials of the instant invention, thus including a 'hydrogel consistency' as claimed herein.

The prior art teaches drug-particle formulation methods entailing similar method steps, used for the same field of endeavor and to treat the same problems as that desired by Applicant(s).

Thus, it is the position of the Examiner that given the explicit teachings of Berg *et al.*, the instant invention, when taken as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

Applicant's arguments filed 12/21/06 have been fully considered.

- **Rejection under 35 U.S.C. 101 – Statutory Double Patenting:**

The 35 U.S.C. 101 Statutory Double Patenting rejections of claims 25-33 over claims 25-33 of 10/293,175 has been hereby *withdrawn*, in view of the fact that the claims entered as a provisional amendment for 10/293,175 were entered in error and were a duplicate of claims 25-33 of application 10/663,181.

- **Rejection under 35 U.S.C. 103(a) over Yang et al. (WO 01/01890):**

Applicant argued, "Yang disclose a "surface treatment" that is accomplished through "either dipping or spraying process." (p. 7, lines 18-20, Yang) In either process, "a solvent carrier" incorporates "the therapeutic agent within the polymer matrix." (p. 7, lines 19-20, Yang) Yang state that the "applied mixture preferably comprises a solvent, a polymer, and a therapeutic agent, with subsequent evaporation of the solvent to leave a polymeric coating." (p. 7, lines 20-23, Yang).

With respect to the first limitation recited above, Yang do not teach, expressly or inherently, adding polymeric particles containing a therapeutic substance to a coating material. Even if polymer particles were added to the "solvent carrier" to form a coating mixture in Yang, there is no teaching or suggestion in Yang that such particles contain a therapeutic agent.

With respect to the second limitation, there is no teaching or suggestion in Yang the polymeric coating that is formed includes polymeric particles containing a therapeutic substance. In particular, there is no teaching or suggestion upon evaporation of the applied mixture of solvent, polymer, and a therapeutic agent results in a coating including polymeric particles containing the therapeutic agent. Although Yang teaches that active agent can be dispersed in the polymer of a coating, there is no express or inherent teaching that the dispersed active agent is within polymeric particles. Additionally, although Yang teaches that the coating can include a blend of first and second co-polymers, there is no teaching or suggestion that the blend includes particles of one polymer dispersed within the other."

These arguments have been fully considered, but were not persuasive. Since Applicant has not defined the size of the polymer particles, the Examiner refers to the teaching of Yang, who uses both hydrophilic and hydrophobic polymers. The active agent is released from the polymer upon the use of a hydrophobic polymer in the solvent. It is the Examiner's position that there is a dispersion and not a solution resulting in polymer particles. Furthermore, it is the Examiner's position that the drug is also dispersed within the polymer mixture. Yang permits the formation of solutions and dispersions. Note that Yang teach hydrophilic and hydrophobic polymers; essentially two embodiments. It is the second embodiment (of a hydrophobic polymer) that the Examiner is relying upon. Applicant's claims fail to recite any particle size.

Furthermore, claim 30 describes water-in-oil emulsions. Thus, Applicant's arguments were not persuasive.

- **Rejection under 35 U.S.C. 103(a) over Berg et al. (US 5,464,650).**

Applicant argued, "Berg do not teach, expressly or inherently, adding polymeric particles containing a therapeutic substance to a coating material. Even if polymeric particles were added to the "solvent" to form the coating solution in Berg, there is no teaching or suggestion in Berg that such particles contain a therapeutic agent. With respect to the second limitation, there is no teaching or suggestion in Berg that the polymeric coating that is formed includes polymeric particles containing a therapeutic substance.

Berg do teach coating a stent with a solution containing solvent with a therapeutic substance "dispersed in fine particles." (col. 3, line 64) In addition, Example 2 of Berg teaches dipping a stent in a "solution with suspended particles of dexamethasone." (col. 5, lines 60-61) However, there is no indication by Berg or the Examiner that a coating with polymeric particles containing therapeutic agent is formed. Thus, there is no express or inherent teaching or suggestion that the dispersed therapeutic agent is within polymer particles.

As with Yang, the Examiner states a conclusion of a prima facie case of obvious without providing any support or argument for it. The "explicit teachings" of Berg do not teach all the claim limitations. Furthermore, the Examiner has provided no motivation or suggestion to modify Berg so that it teaches the above-mentioned claim limitations."

Applicant's arguments have been fully considered, but were not persuasive. Berg, at column 5, lines 12-18, is suggestive of a polymeric matrix formed in a solution that traps the drug depending on the ratio of the therapeutic substance to polymeric agent. Furthermore, the Examiner points out that there is no degree of drug loading recited in the claims. Thus, Applicant's arguments were not persuasive.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

--No claims are allowed at this time.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday through Friday from 8:00A.M. to 5:30P.M., alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

HUMERA N SHEIKH
PRIMARY EXAMINER

Art Unit 1615

March 19, 2007

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